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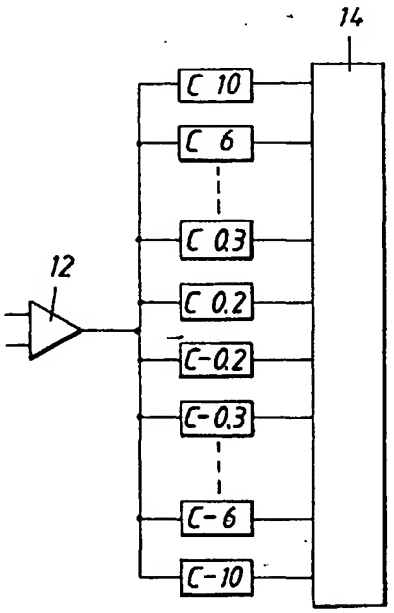
(54) A cardiac event detecting system for a heart stimulator

(57) A cardiac event detecting system for an implantable heart stimulator intended to be connected to the heart of a patient through at least two unipolar electrode leads or at least one bipolar electrode lead having one eletrode pole in the atrium and one electrode pole in the ventricle for sensing heart signals comprises at least two signal channels for signals sensed between the two electrode poles and between one of the electrode poles and the stimulator capsule respectively. Each signal channel comprises signal processing means (12; C10, C6 ... C0.3, C0.2, C-0.2, C-0.3 ... C-6, C-10; 14). A decision logic means is provided for comparing the signals from the two signal channels with signal criteria for detecting the occurrence of a cardiac event. A/D-converting means (C10, C6 ... C0.3, C0.2, C-0.2, C-0.3 ... C-6, C-10) are provided for converting sampled values of said sensed heart signals into digital words for each signal channel. The decision logic is adapted for comparing the digital words and their differences with the criteria for determining the occurrence of a cardiac event.

Fig.3



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Description

Technical Field

[0001] The present invention relates to a cardiac event detecting system for an implantable heart stimulator intended to be connected to the heart of a patient through at least two unipolar electrode leads or at least one bipolar electric lead having one electrode pole in the atrium and one electrode pole in the ventricle for sensing heart signals, said detecting system comprising at least two signal channels for signals sensed between the two electrode poles and between one of the electrode poles and the stimulator capsule respectively, each signal channel comprising signal processing means, and a decision logic means for comparing the signals from the two signal channels with signal criteria for detecting the occurrence of a cardiac event.

Background Art

[0002] In connection with cardiac pacing there is a general desire to be able to use unipolar electrodes instead of bipolar ones. Bipolar electrodes comprise two helically wound conductors connected to the electrode tip and ring respectively, which make the electrode more stiff and more frequently defective than a unipolar electrode which only comprises one helically wound conductor.

[0003] In connection with heart signal detection there are conflicting requirements. Thus a detecting level must be used for an absolutely reliable detection of the wanted heart signals even at amplitude variations due to e.g. normal physiologically dependent amplitude variations, different heart signal origins, and possible variations in the electrode position. Further a detecting level should be used for an absolutely reliable rejection of non-wanted signals, such as muscle interferences, far field heart signals and T-waves. A detecting level should also be used for most probable rejection of non-wanted external interferences. A reliable automatic adaption of the detecting level is also highly desirable.

[0004] A large number of different heart signal detectors is previously known. Normally these detectors comprise an amplifier with some kind of band-pass filter and one single signal amplitude comparator for determining whether a detection criterion is fulfilled or not. This is also the case in different types of adaption systems having a second "parallel" detector. Also in these latter systems the detection decision is emanating from a comparison in only one comparator.

[0005] Thus in US-A-5,058,599 a method and an apparatus for detecting a sequence of abnormal events in the depolarization signal of a heart are described. A selective signal parameter is then compared to a defined threshold and the maximum value is measured of the signal parameter for each event which exceeds the threshold. The described method and apparatus are particularly well suited for detecting a sequence of events indicating fibrillation.

[0006] Detection of electrical events in the heart by measurements between an electrode pole in the atrium, an electrode pole in the ventricle and the heart stimulator enclosure are also previously known, see e.g. US-A-5,607,457, EP-A 0 596 319 and EP-A 0 646 390.

[0007] US-A-5,607,457 relates to an evoked response detector comprising unipolar electrodes in the atrium and the ventricle. A differential detector is connected to the electrode leads and detects cardiac activity between the atrial electrode and ventricular electrode. A correlation detector is connected between the pacemaker housing and one of the atrial or ventricular electrodes to generate a correlation signal identifying whether the detected cardiac activity arise in the atrium or in the ventricle.

[0008] EP-S 0 596 319 discloses a heart stimulator comprising an electrode system of at least one bipolar electrode with one pole positioned in the atrium and one pole in the ventricle, or at least two unipolar electrodes arranged in the atrium and the ventricle respectively. Atrial activity is measured between the two poles of the bipolar electrode or between the two unipolar electrodes and ventricular activity is measured between the ventricular pole or electrode and the stimulator housing.

[0009] Also EP-A 0 646 390 describes measurement between an atrial and a ventricular electrode and measurement between the ventricular electrode and the heart stimulator housing for detecting spontaneous and evoked heart responses. One atrial comparator and one ventricular comparator are provided for comparing measured signals with an atrial reference potential and a ventricular reference potential respectively.

[0010] US-A-4,905,708 discloses an apparatus for recognizing cardiac arrhythmias. Analogue signals obtained by sensing at the heart or on the body of the patient are then digitized and a first differentiation of the digitized signals is carried out. A gradient pattern detector compares the differentiated signals with normal differentiated signals detected during sinus rhythm. Differences between the differentiated signals are indicative of pathological tachycardia, the nature of which can be identified by comparison with pre-programmed signals of like type.

[0011] The purpose of the present invention is to provide a new cardiac event detecting signal system for a heart stimulator, which detecting system makes a more reliable detection possible than with prior art detectors.

Disclosure of the Invention

[0012] This purpose is obtained by a cardiac event detecting system according to the introductory portion of the description and with the characterizing features of claim 1.

[0013] Thus with the detecting system according to the invention a plurality of combined function criteria is

used for the detection decision. In the detecting system according to the invention several simultaneous parallel signal processings are performed and from a plurality of combined "individual" detections prevailing heart signal activity is identified. With the detecting system according to the invention it will also be possible to distinguish between the occurrence of different cardiac events. Thus, by digital processing of the digital words obtained the following distinct cardiac events can be distinguished, namely cardiac event in the atrium (P-wave), cardiac event in the ventricle (R-waves), cardiac signals which shall be omitted, interference received on the stimulator capsule, and no cardiac activity. Each event has its own pattern or word and the detection process is formed of the procedure for deciding of occurrence of a specific event.

[0014] According to an advantageous embodiment of the system according to the invention said converting means comprise a set of comparators provided in each one of said signal channels, each comparator having a specific reference level for comparing said sampled values of said sensed heart signals with said reference levels, and in that a digital converter is provided for presenting the result of the comparisons in the form of said digital words of a "0" or a "1" for each comparator depending on whether the sampled signal value is above or below the reference level in question. By performing several multi-amplitude signal detections simultaneously in this way a quicker A/D conversion is obtained.

[0015] According to an advantageous embodiment of the system according to the invention adjacent reference levels of the said comparators are separated logarithmically with 30-70%. Such an exponential distribution of the reference levels requires less digital bits when a specific resolution is required for low level signals, and the distribution gives a constant relative accuracy for different amplitude levels in the following decision process. For example, each level of the above mentioned exponential distribution can be described by three digital bits. The same resolution for low levels and the same dynamic range require five bits with a linear A/D conversion.

[0016] According to other advantageous embodiments of the system according to the invention a reference value creation unit is provided to adaptively adjust the reference values of the comparators. Such an adaption process is of importance since the determination of the discrimination level for the lowest acceptable levels of R-waves and P-waves have to be related to the noise level. The adaptive adjustment process can be started by an external order, or be performed at regular time intervals, or reference values can be continuously adapted as functions of sensed signals, or the adaptive adjustment process can be started in response to the detection of a significant change in the sensed signals.

[0017] In the detecting system according to the invention influence from external interference is eliminated to a greater extent than in previously known heart signal detecting systems. In the determination process related to a possible cardiac event or specific heart signal all electrode combinations, time relations of the measured signals and information about the signal shapes are used to distinguish the signal information.

Brief Description of the Drawings

[0018] To explain the invention in greater detail embodiments of the invention, chosen as examples, will now be described with reference to the enclosed drawings, on which

Figure 1 shows schematically a pacemaker with an atrial and ventricular electrode connected to the heart of a patient,

Figure 2 shows the circuit of a logarithmic analogue amplifier suitable for use in connection with the A/D conversion in the system according to the invention.

Figure 3 shows a circuit used in the system according to the invention for generating digital words representing measured signals,

Figure 4 shows the connections of an IC-component of a heart stimulator,

Figure 5 shows an embodiment of an input stage of an A/D-converter in the form of a delta modulator used in the system according to the invention,

Figure 6 shows the typical basic block used in a switched capacitor network for the realization of the system according to the invention,

Figure 7 is a schematic overall view of a typical heart stimulator comprising the detecting system according to the invention,

Figure 8 shows the circuitry of the signal processing and detection logic in figure 7 more in detail,

Figure 9 shows in the form of a more detailed block diagram the detection logic in figure 8.

Figure 10 shows an example of the signals on the two signal channels and the output signal from a similarity logic as functions of time,

Figure 11 shows in more detail the circuitry of the reference creation logic in figure 8, and

Figure 12 shows table I illustrating processed signals sampled in time with equal time partition.

Description of Preferred Embodiments

[0019] The detecting system according to the invention is intended to be used in a heart stimulator with at least one unipolar electrode 4 in the ventricle and one unipolar electrode 6 in the atrium, see figure 1. In addition thereto also the capsule 8 of the heart stimulator 3 is used as one electrode.

[0020] Instead of two unipolar electrodes a bipolar electrode can be used having one electrode pole in the atrium and one pole in the ventricle.

[0021] The detecting system according to the inven-

tion can also be used in a heart stimulator with at least two electrodes in one and the same heart chamber, provided that the electrodes are separated by a distance of sufficient length.

[0022] The detecting system according to the invention comprises electronics for signal processing in several steps, as will be described in more detail below. Thus these electronics comprise at least two amplifiers, illustrated at 1, 2 in figure 1, and passband and slow-rate filters with predetermined properties.

[0023] The amplifiers 1, 2 are connected in two signal channels. Thus the inputs of the amplifier 1 is connected to the ventricular electrode 4 and the stimulator capsule 8 and the amplifier 2 between the ventricular 4 and the atrial 6 electrodes.

[0024] The block 10 of the heart stimulator 3 in figure 1 contains the rest of the electronics of the heart stimulator 3, like comparators, digital signal processing means, stimulating pulse generating means etc.

[0025] For A/D-converting the measured analogue signals different A/D-converting techniques which are known per se can be used. Thus A/D-converting means with successive approximations can be used, i.e. a procedure of iterative digital up/down counting until the digital value corresponds to the analogue input signal.

[0026] Alternatively A/D-converting means in the form of a slope converter can be used. In such a converter the measured analogue signal is charging a capacitor for a predetermined time, determined as a predetermined number of clock pulses. The resulting voltage on the capacitor will then be proportional to the analogue signal. In the next step the analogue signal is disconnected and the capacitor is discharged to a known load. The discharge time is measured by counting clock pulses. Thus the count corresponds to the value of the analogue signal.

[0027] Also so-called delta/sigma converters can be used. The measured analogue signal is then compared with reference levels which are successively changed up or down by 1 bit till the level of the analogue signal is reached. An average of a number of up/down counts gives the A/D-converted value.

[0028] So-called flash converters are preferred in the system according to the invention. These converters comprise a large number of parallel comparators to which the analogue signal is supplied for simultaneous comparison in all the comparators. All the comparators are switched simultaneously according to the result of the comparison and the corresponding digital word is directly obtained.

[0029] In the above mentioned A/D-converters the conversion can be "linear", i.e. a "linear" analogue input signal is supplied to A/D-converting means in which linear steps are used in counting and comparing procedures. However, it can be an advantage to transfer the measured analogue signal into a "logarithmic" signal before the A/D-conversion. For this transfer into a logarithmic form a logarithmic analogue amplifier of the kind shown in figure 2 can be used. The input signal U_{in} is then through a resistor R_{in} supplied to a circuit comprising two anti-parallel connected diodes 7, 9 forming a feedback loop for the amplifier 11. On the output of this circuit an output signal U_{out} is produced related to the input signal U_{in} as follows.

[0030] For

$$U_{in} > 0\ U_{out} = -\log|U_{in}|$$

$$U_{in} > 0\ U_{out} = -\log|U_{in}|$$

$$U_{in} = 0\ U_{out} = 0$$

[0031] A direct logarithmic conversion can be performed in a flash converter if the reference values of the comparators are logarithmically separated.

[0032] An embodiment of such a flash converter will be described below with reference to figure 3.

[0033] Figure 3 shows an example of a circuit contained in block 10 in figure 1 for converting measured analogue signals into digital words. The measured or sampled signals are supplied to a set of comparators C10, C6 ... C0.3, C0.2, C-0.2, C-0.3 ... C-6, C-10 through an amplifier and bandpass filter 12. In the comparators C10 ... C-10 the input signals are compared with different reference levels. These reference levels can typically range from 0.2 mV to 10 mV with a logarithmic spacing of 30-70% between neighbouring comparators. Both positive and negative reference levels are used.

[0034] The binary output signals from the set of parallel working comparators C10 ... C-10 produce at an output digital converter 14 two digital words or patterns representing a sample of the signals measured in the two signal channels defined in figure 1.

[0035] The digital words received from the comparators C10 ... C-10 can either be continuously processed in following detecting stages as soon as they are produced or they can be sampled according to a predetermined time sequence and stored as a number of digital words and these stored digital words can then be used in the subsequent detecting procedure.

[0036] Thus, the input signal is compared to the reference level of each of the comparators C10 ,... C-10 and a "1" is obtained from those comparators where the input signal exceeds the reference level. From the other comparators the output signals are "0". The output signals from the comparators consequently give a set of "1" and "0" representing the input signal at a given time, e.g. 00111111, which indicates that the two comparators with the highest reference levels give "0" as output signals and the rest of the comparators give "1". This sequence of "0" and "1" is then translated into the digital figure 0110 (=6) which forms the word in question. A sequence of words will in this way be generated representing the signals from the two signal channels as mentioned above and also the difference between the

words is formed. These three sequences are compared with criteria for occurrence of P-wave, R-wave, muscle noise etc. which makes the identification of a detected cardiac event more reliable.

[0037] For the occurrence of a R-wave the sequence of words from channel 1 in figure 1 can typically be 0 +2 -5 -6 -2 0 and the sequence of words from channel two 0 +1 -4 -6 -3 -1.

[0038] The criteria for R-wave detection can be

Word 1 sequence <-2, <-4, <-1
Word 2 sequence <-2, <-4, <-1
Word 1 - word 2 sequence ±1, ±1, ±1.

[0039] All these conditions must be fulfilled for a detected cardiac event to be identified as an R-wave.

[0040] The criteria for P-wave detection could be

Word 1 sequence <+1, <+1, <+1
Word 2 sequence >+1, >+3, >+1

[0041] As appears from the above example the word 1 and word 2 sequences of the R-wave detection criteria are similar, whereas there is a significant difference between the corresponding sequences of the P-wave detection criteria. This depends on the fact that the R-wave is much stronger than the P-wave. Thus the sensitivity of channel 1 which measures the signal between the ventricular electrode 4 and the stimulator capsule 8 can be adjusted such that only ventricular events are detected, whereas the sensitivity of channel 2 which measures the signal between the ventricular and the atrial electrodes 4, 6 is adjusted such that both atrial and ventricular events are detected. Consequently for an R-wave the word 1 sequence and the word 2 sequence will be essentially equal, whereas for P-waves there is a significant difference between the word 1 sequence and the word 2 sequence, since a P-wave is only detected in channel 2. This circumstance appears from the example above.

[0042] For muscle noise the word sequence can typically be +2 +1 0 -2 +1 -1 0 and the muscle noise detection criteria can be

Word 1 sequence >+1 or <-1
Word 2 sequence ≤+1 and ≥-1.

[0043] A higher noise level is normally received on channel 1 which is connected to the stimulator capsule 8. No activity signals gives low level words which can be considered as "noise" words. R- and P-waves give "higher level" words. These higher level words must be distinct and different from the noise-level words to give detectability. By utilizing the fact that noise is substantially appearing only in that signal channel which comprises the stimulator capsule for changing the R-wave and P-waves discriminating levels when muscle noise appears an automatic change of the R-wave and P-wave discriminating levels, when muscle noise appears, can be provided. This change of discriminating levels is an adaptation process such that the lowest acceptable levels of R-wave detection and P-wave detection respectively together with the noise level will determine the discrimination level. The detecting system according to the invention is consequently provided with an automatic sensing threshold setting function.

[0044] As mentioned above, according to one example of the detecting system according to the invention five distinct cardiac events in this way can be distinguished by digital signal processing of the digital words received from the comparators C10 ... C-10. These cardiac events are a) occurrence of an atrial event (P-waves), b) occurrence of a ventricular event (R-waves), c) other cardiac signals which shall be omitted, d) interferences received on the heart stimulator capsule, and e) no cardiac activity. Each event has its own pattern or word and the detection process consists in the decision of occurrence of an identified event.

[0045] Figure 4 shows the connections of an IC-component used in a heart stimulator provided with a detecting system according to the invention. Thus there are three connections for the atrial lead, the ventricular lead, and for connection to the stimulator capsule respectively. The connections for the atrial lead and the ventricular lead are designed for both delivery of stimulation pulses, "output stim", and for receiving sensed signals, "signal input". Both connections are provided with a high frequency filter for removing radio frequency interferences etc. and an anti-aliasing-filter for removing frequencies above the used sampling frequency. The sampling frequency is typically in the range of 20-500 Hz, i.e. a plurality of samples is taken during a cardiac cycle. A capacitor C_3 is also provided in each connection for removing DC-components.

[0046] Figure 5 shows an input stage to an A/D-converter in the form of a delta modulator, suitable for use in the detecting system according to the invention. Analogue measurement signals are then converted into a digital bit stream through a comparison procedure at 16, controlled by an up/down logic 18.

[0047] Figure 6 shows a basic block formed of capacitors C_1, C_2, and switches for switched capacitor networks. Networks of such blocks are suitable for use in the detecting system according to the invention for realizing such signal processing as bandpass filtering - a passband of 23-180 Hz is appropriate for the system according to the invention - signal integration, etc. The processing properties are determined by the relation between capacitor values in the basic blocks and the way of connecting the blocks. Thus, if, for example, the block is placed in a forward signal path the signal processing properties will be different from the signal processing properties if the block is connected in a feedback path.

[0048] To construct suitable switched capacitor networks is previously known and will not be described in

more detail in this connection.

[0049] Figure 7 shows a block diagram of a heart stimulator comprising a cardiac event detecting system according to the invention.

[0050] On the input side two delta modulators 20, 22 are provided for differentially processing the signals between the atrial and ventricular electrodes and between the ventricular electrode and the stimulator capsule respectively. As an alternative the delta modulator 22 can be connected to a signal channel formed of the atrial electrode and the capsule.

[0051] The delta modulators 20, 22 are connected to a signal processing and detection logic 24 comprising a bandpass filter 26, 28 in each signal half, cf. figure 8.

[0052] On the output side of the signal processing and detection logic 24 of the heart stimulator in figure 7 a mode switch logic 84 is connected for being activated in case of the detection of atrial fibrillation. Further refractory time means 86 are adapted to introduce a refractory time into the pacemaker timing logic 88 in response to the detection of a P-wave or a R-wave. The heart stimulator also comprises atrial and ventricular stimulation means 90, 92 controlled by the pacemaker timing logic 88. A blanking control 94 is further connected between the pacemaker timing logic 88 and the delta modulators 20, 22 for preventing inappropriate detection of signals during a blanding period starting with the delivery of a stimulation pulse.

[0053] A reed-element 96 and telemetry communication means 98 are connected to the pacemaker timing logic 88 for making external control of the heart stimulator possible.

[0054] The signal channel comprising the stimulator capsule may pick up also external interference signals, such as muscle noise, as discussed above. For determining the noise level the signal processing and detection logic 24 comprises signal averaging means 30, see figure 8, in which rectified average values of the noise signals is formed in an averaging process.

[0055] In the averaging means 30 the noise level can be determined as the average signal during a specific time, for example during one second. The average value can be determined by the use of a counter adding the A/D-converted binary values, without the sign, e.g. for each millisecond. The average noise level value is then 1/1000 of the counter value.

[0056] Alternatively the averaging means 30 can comprise a digital recursive filter for producing a running average value. The determined noise level is used in an adaptation process to change the reference values for the detection of different cardiac events. This process takes place in the reference creation logic 40.

[0057] When there is a signal level above zero on that signal path which is connected to the stimulator capsule, no signal is preferably added to the noise averaging process in the averaging means 30.

[0058] The delta modulator 20 which is connected to the signal channel comprising the atrial electrode is connected to atrial fibrillation detecting means 32 in the signal processing and detection logic 24. The signal processing means 32 is devised for slope/time processing of the output signal from the delta modulator 20 and comparison with a reference value S_{aref}. The signal processing means 32 is connected to a detection logic 34 for determining whether atrial fibrillation, AF, is present or not. Thus, in the slope/time processing means 32 it is determined whether the slope of the signal is exceeding a predetermined limit and if this condition is fulfilled for a period of time also exceeding a predetermined limit. If both these conditions are fulfilled the existence of atrial fibrillation is determined in the detection logic 34. If P-waves are detected the "slope time processing means" 32 is disconnected.

[0059] After analogue signal processing an A/D signal converter is provided in each single channel for converting the analogue measurement signals into figures of amplitude and sign. Also this A/D conversion can be realized with the aid of a switched capacitor network. A suitable solution is to use a set of amplitude comparators in the switched capacitor network of the kind described above in connection with figure 3. These sets of comparators are represented by the blocks 36 and 38 respectively in figure 8. The reference levels of the comparators can be, as described in connection with figure 3, accurately determined in an easy way by choosing suitable relative capacitor values in the network. The levels of the comparators are preferably selected as an exponential sequence, e.g. 0, 0.50, 0.77, 1.2, 1.8, 2.8, 4.3, and 6.5 mV and with both positive and negative levels. By such an exponential distribution of the reference levels two advantages are obtained, namely a lower number of digital bits for a specific resolution for low signal levels, and a constant relative accuracy for different amplitude levels in the following decision process. Each level on the above exponential distribution can be described by three digital bits. To get the same resolution for low levels and the same dynamic range five bits are required with a linear A/D-conversion.

[0060] A comparator 42 is also arranged in the signal channel connected to the atrial and ventricular electrodes for comparing the signal on this channel with the reference value R_{aref} for detection of R-waves, since both P-waves and R-waves appear in the signal on this channel.

[0061] In the decision logic 34 the processed signals from the two signal paths comprising the atrial and ventricular electrode and the ventricular electrode and the stimulator capsule respectively are compared to reference values R_{aref} for R-waves, P_{aref} for P-waves and S_{aref} for the slope of the signal for atrial fibrillation detection, said reference values being created by the adaptive process described above. The signal on the channel comprising the atrial and ventricular electrodes are compared in the comparators 44, 46, 48 with respective reference values R_{aref}, P_{aref}, and S_{aref} for R-wave, P-wave, and atrial fibrillation, see figure 9 which

shows the decision logic 34 in figure 8 in more detail. The signal on the other signal channel comprising the ventricular electrode and stimulator capsule is compared in the comparator 50 with the reference value R_{aref} for R-wave and this signal is also supplied to a noise level meter 52 for determining the noise level as described above. In a similarity logic 54 the signals from the two channels are compared. In this comparison process the noise level is considered, too.

[0062] The output signals from the comparators 44, 46, 48, 50 and from the similarity logic 54 are supplied to a R-wave logic 56, a P-wave logic 58 and an AF detecting logic 60, in which R-wave, P-wave and AF indications are decided.

[0063] A rate check is also performed in the decision logics 56, 58, 60.

[0064] There are four states which have to be distinguished by the decision logics 56, 58, 60 in figure 9, namely 1) P-wave, 2) R-wave, 3) atrial fibrillation, and 4) no signal.

[0065] From the sensed data it shall be decided which of the above four events takes place at each time.

[0066] If a similarity between the signals on the two channels is detected by the similarity logic 54, a detected event must be a R-wave since R-waves appear on both channels as discussed above. When a R-wave is detected the P-wave logic 58 is disabled.

[0067] In case of non-similarity between the signals on the two channels detected by the similarity logic 54 a detected cardiac event is decided to be a P-wave or atrial fibrillation. In case of detecting a P-wave in the P-wave logic 58 the AF detecting logic 60 is disabled.

[0068] In the decision process time relations between the occurrence of different cardiac events are also considered. For example, a R-wave cannot appear within 280 msec from the previous R-wave. A P-wave cannot appear within 280 msec from the previous P-wave. An atrial fibrillation shall appear within 150-400 msec from the previous one and the shape criteria of the fibrillation signal shall be within maximum and minimum slope criteria and within maximum and minimum slope duration. Thus also such time relations are considered in the decision logics 56, 58, 60.

[0069] The processed signals can either be digital in amplitude and analogue in time as shown in figure 10 a and b or sampled in time with equal time partition as illustrated in table I, in Figure 12.

[0070] In figure 10 channel 1 shows the signal sensed between the atrial and ventricular electrode and channel 2 the signal between the ventricular electrode and the stimulator capsule. The P-wave appears in the signal on channel 1 but not on the signal on channel 2 whereas the R-wave appears in the signals on both channels. Figure 10c shows the output signal from the similarity logic 54 comparing the similarity of the signals from the two channels.

[0071] A detected cardiac event is a P-wave when the following criteria are satisfied:

Channel 1 (value) $\geq P_{aref}$
Channel 1 (sign) = sign(P_{aref})
Channel 2 (value) $< R_{aref}$
Channel 2 (sign) = any
Similarity = 0.

[0072] A cardiac event is decided as a R-wave if the following criteria are satisfied:

Channel 1 (value) = any
Channel 1 (sign) = any
Channel 2 (value) $\geq R_{aref}$
Channel 2 (sign) = sign(R_{aref})
Similarity = 1

[0073] More complex decision criteria can include the satisfaction of a certain time sequence. For accepting a detected cardiac event as a P-wave each value relation above shall be fulfilled at three times, i.e.

Channel 1 (value 1) $\geq P_{aref1}$
Channel 1 (sign 1) = sign(P_{aref1})
Channel 2 (value 1) $< R_{aref(max)}$
Channel 1 (value 2) $\geq P_{aref2}$
Channel 1 (sign 2) = sign(P_{aref2})
Channel 2 (value 2) $< R_{aref(max)}$
Channel 1 (value 3) $\geq P_{aref3}$
Channel 1 (sign 3) = sign(P_{aref3})
Channel 2 (value 3) $< R_{aref(max)}$

[0074] At least one similarity data at the maximum of the stored P (value) = 0.

[0075] The reference values R_{aref}, P_{aref}, and S_{aref}, and possible other reference values depending on the complexity of the decision process are stored. These reference values are created from the acquired signal data and are successively updated.

[0076] The calculation of the reference values are performed in the reference creation logic 40 in figure 8 and updating the reference value can take place e.g. by external order, through telemetry control, on a regular basis in the heart stimulator, continuously from a start time, in case of a significant change in the statistical processing of input data. The reference creation logic is shown in greater detail in figure 11. The collecting of values for statistical or average calculations in the detecting system according to the invention are performed according to specified criteria.

[0077] If the signal on the channel comprising the atrial and ventricular electrodes has a value $\geq P_{aref}$, determined in the comparator 46, a new value is expected and the maximum value is collected by peak signal sampling means 62, 64, see figure 11. Similarity between the two channels is recorded by the similarity logic 54 and the time from previous collected data with the same type of similarity is checked to be within the time criteria. If the similarity and the sign are satisfied for a P-wave or a R-wave the value is transferred to

average calculating means 66, 68 or to means for performing other statistical processes.

[0078] If there is an interference level above a specified threshold value on the channel connected to the stimulator capsule this is determined by the noise level meter 52. No collecting and updating of the reference values are then performed. Thus in this case the noise level meter 52 disables the collection of signal data by means of a comparator 70 in which the measured noise level is compared to the predetermined acceptable maximum threshold value.

[0079] If a more complex detection or decision process with time sequences is used additional data are used for the average process. Values also before and after the maximum value are then used and co-ordinated with the respective reference time for the average determining process. For example if P_{a2} is the measured maximum value, P_{a1} is a value measured 4 msec before the maximum and P_{a3} the value measured 4 msec after the maximum value also average values of P_{a1} and P_{a3} are calculated. These average values may e.g be calculated for the last 16 values.

[0080] The average values can also be determined by recursive filtering. New values are then always added and 1/256 of the actual sum is subtracted. The sum shifted by 8 bits, which is equal to division by 256, is then used as the average heart signal amplitude.

[0081] The calculated average values P_a and R_a are stored in memory means 72, 74 together with their signs and adjustment means 76, 78 are connected to these memory means 72, 74 for momentary adjustment of P_a and R_a respectively.

[0082] The noise level meter 52 is connected to the adjustment means 78 for inhibiting the momentary adjustment of R_a, if the noise level exceeds the allowed maximum threshold value, as discussed above.

[0083] The reference creation logic also comprises calculation and memory means 80 for calculating the average value S_a of the specific signal slope for use in connection with the detection of atrial fibrillation from the signals on the channel comprising the atrial and ventricular electrodes. Adjustment means 82 are also provided for momentary adjustment of the existing reference value S_{aref} by the last calculated and stored S_a to update S_{aref}.

[0084] Also the adjustment means 76, 82 for P_a and S_a respectively are connected to the noise level meter 52 for inhibition of the updating process when the noise level exceeds the maximum allowed threshold value.

[0085] For many applications the adjustment means 76, 82 for P_a and S_a is not needed and can be omitted.

[0086] An interference adjustment of the S_{aref} is not needed if a combipolar connection or a bipolar atrial electrode is used for the atrial fibrillation detection.

[0087] The determined reference values P_{aref} and R_{aref} are used in comparators for comparing the processed input signals with these reference values in the decision process, as described above. The values P_{aref} and R_{aref} can be e.g. 2 steps below the corresponding average values and the limits P_{aref} and R_{aref} for detection of a P-wave and a R-wave respectively can be at least two steps above the determined average noise level. This means that P_{aref} or R_{aref} can be momentarily adjusted in a noisy situation by one step to avoid false detections due to noise while still having a high probability of heart signal detection. However, adjustment by two steps cannot be allowed. Instead a too noisy situation then has to be indicated and the heart stimulator is controlled to stimulate the patient's heart asynchronously with an interference rate.

[0088] For the detection of atrial fibrillation separate signal processing takes place for determining the specific heart signal morphology and rate. The fibrillation signals may have an amplitude of the same order or magnitude as P-waves but are often much lower. Further the slopes of the signals are often lower than those of normal heart signals and the signal intervals are often irregular and shorter than 400 msec but longer than 150 msec. A suitable signal processing can comprise e.g. a signal slope follower, at unit 48 in figure 8, and information about the signal slope is combined with a signal duration criterion in the AF detection logic 60 for determining whether atrial fibrillation exists or not. As long as normal P-waves are detected there is no need to check possible occurrence of atrial fibrillation. In the absence of detected P-waves, the atrial fibrillation function of the detecting system according to the invention is activated. The amplitude criteria is determined with the aid of a reference value S_{aref}. This reference value can be based on the reference value P_{aref}. If a signal duration is fixed to e.g. 8 msec the P_a value can be used to calculate the slope criterion. The slope reference value S_{aref} can be calculated as a certain percentage, e.g. 50% of Pa × 1000/8 ≅ 50% of Pa × 128. Thus the reference value $S_{aref} = Pa \times 64$ which is easily calculated by shifting a binary data 6 bits if the P_a value exists in linear binary form.

[0089] The detecting system according to the invention exhibits several advantages from a constructional point of view. Thus amplifiers and filters can be conventionally designed. Programming circuitry and registers for the detection are omitted which saves space. Comparators can be designed with relatively small surface compared with the amplifiers. If the analogue signal is processed in a switched capacitor network the comparators and the comparator reference levels are easily built in as parts of the switched capacitor network with very low extra space requirements. The digital logic required for the processing of the digital words as described above requires some space in the integrated circuit forming the detecting system, but requirements of digital logics are very small compared to requirements for analogue processing in this regard.

[0090] The decision making functions of the detecting system according to the invention are realized by digital technique.

[0091] The A/D-conversion can be performed at different stages of the signal processing. Therefore, as an alternative to the above described embodiments comprising two delta modulators, A/D-converters can be provided at the input side of the detecting system for creating amplitude values with enough resolution. Ordinary digital signal processing is then performed instead of signal processing with the aid of switched capacitor networks.

Claims

1. A cardiac event detecting system for an implantable heart stimulator intended to be connected to the heart of a patient through at least two unipolar electrode leads or at least one bipolar electrode lead having one electrode pole in the atrium and one electrode pole in the ventricle for sensing heart signals, said detecting system comprising at least two signal channels for signals sensed between the two electrode poles and between one of the electrode poles and the stimulator capsule respectively, each signal channel comprising signal processing means, and a decision logic means for comparing the signals from the two signal channels with signal criteria for detecting the occurrence of a cardiac event, **characterized in** that A/D converting means are provided for converting sampled values of said sensed heart signals into digital words for each signal channel, said decision logic being adapted for comparing said digital words and their differences with said criteria for determining the occurrence of a cardiac event.

2. The system according to claim 1, **characterized in** that said A/D converting means comprise a set of comparators (C10, C6 ... C0.3, C0.2, C-0.2, C-0.3 ... C-6, C-10; 14) provided in each one of said signal channels, each comparator having a specific reference level for comparing said sampled values of said sensed heart signals with said reference levels, and in that a digital converter is provided for presenting the result of the comparisons in the form of said digital words of a "0" or a "1" for each comparator depending on whether the sampled signal value is above or below the reference level in question.

3. The system according to claim 1, **characterized in** that said A/D converting means comprise a set of comparators provided for digitizing the difference between the signals from the two signal channels.

4. The system according to claims 2 or 3, **characterized in** that adjacent reference levels of said comparators are separated logarithmically with 30-70%.

5. The system according to any of the claims 2 through 4, **characterized in** that said reference levels comprises both positive and negative level values.

6. The system according to claim 1, **characterized in** that each A/D converting means comprises a delta modulator as input stage.

7. The system according to any of the preceding claims, **characterized in** that said decision logic means is arranged to continuously receive said digital words for comparison with said criteria.

8. The system according to claim any of the claims 1 through 6, **characterized in** that a storing means is provided for storing said digital words and in that sequences of such stored words are supplied to said decision logic means for comparison with said criteria.

9. The system according to any of the claims 1 through 6, **characterized in** that a storing means is provided for storing said digital words and in that said decision logic means comprises sampling means for sampling said stored words at sequential times for comparing sampled words with said criteria.

10. The system according to any of the preceding claims, **characterized in** that said decision logic means comprises a similarity logic for comparing sensed signals from different signal channels for determining mutual signal similarity.

11. The system according to any of the preceding claims, **characterized in** that a reference value creation unit is provided to adaptively adjust the reference values of the comparators.

12. The system according to claim 11, **characterized in** that said reference value creation unit is activatable to start an adaptive adjustment process by an external order, delivered telemetrically to the reference value creation unit.

13. The system according to claim 11, **characterized in** that said reference value creation unit is activatable to adaptively adjust the reference values at regular time intervals.

14. The system according to claim 11, **characterized in** that said reference value creation unit is continuously adapting said reference values as functions of said sensed signals.

15. The system according to claim 11, **characterized in** that said reference value creation unit is activatable to start an adaptive adjustment process in

response to the detection of a significant change in the sensed signals.

16. The system according to any of the claims 11 through 15, **characterized in** that said reference value creation unit comprises an average value calculating means including a counter adding A/D converted binary signal values, without the sign, for determining the average value during a predetermined time.

17. The system according to claim 16, **characterized in** that said average value calculating means comprises a digital recursive filter for creating a running signal average value.

18. The system according to claims 16 or 17, **characterized in** that said average value calculating means is controllable to operate at specific times.

19. The system according to any of the preceding claims, **characterized in** that a slope/time processing means is connected to the signal channel intended to be connected to an electrode positioned in the atrium, said slope/time processing means being connected to an atrial fibrillation detecting unit for comparing processed signal characteristics with signal criteria for determining the occurrence of atrial fibrillation.

20. The system according to claim 19, **characterized in** that said atrial fibrillation detection unit is controllable to be inhibited in response to the detection of a P-wave.

21. The system according to any of the preceding claims, **characterized in** that an averaging means and a noise determining unit are connected to the signal channel connected to the stimulator capsule for determining the noise level.

22. The system according to claim 21, **characterized in** that said reference value creation unit is connected to said averaging means for inhibiting the reference value adjustment, if the noise level exceeds a predetermined threshold.

23. The system according to any of the preceding claims, **characterized in** that said signal processing means comprises a band pass filter having a passband between 20 and 180 Hz.

24. The system according to any of the preceding claims, **characterized in** that said signal processing means comprises a slew rate filter.

25. The system according to claim any of the preceding claims, **characterized in** that said comparators of said A/D converting means and said signal processing means are realized by switched capacitor networks.

26. The system according to any of the preceding claims, **characterized in** that said decision logic means is adapted to receive over a plurality of signal channels signals sensed by different electrode combinations to discriminate signal information for determining cardiac events by a multi-criteria comparison procedure.

27. An implantable heart stimulator, intended to be connected to the heart of a patient through at least two unipolar electrode leads or at least one bipolar electrode lead having one electrode pole in the atrium and one electrode pole in the ventricle for sensing heart signals, **characterized by** a cardiac event detecting system according to any of the preceding claims.

Fig.1

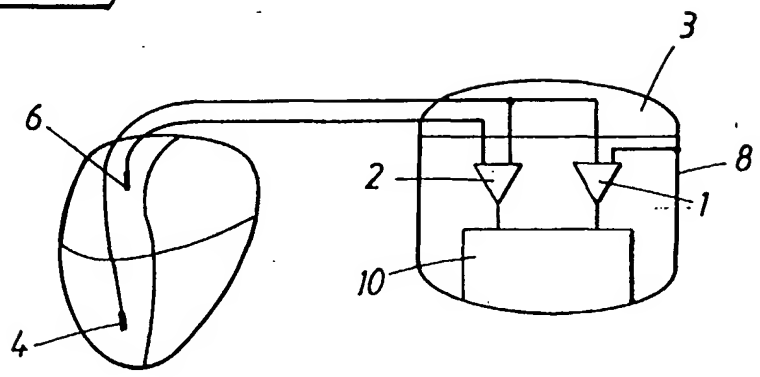

Fig.2

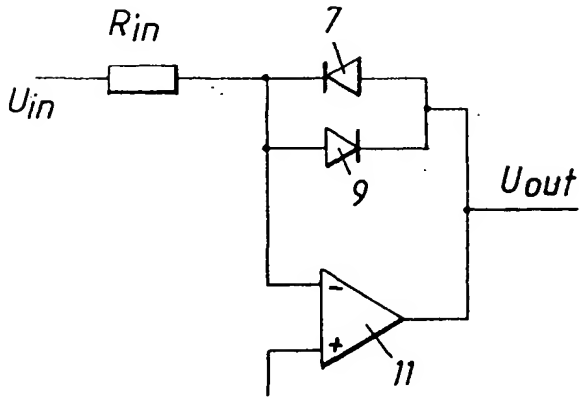

Fig.3

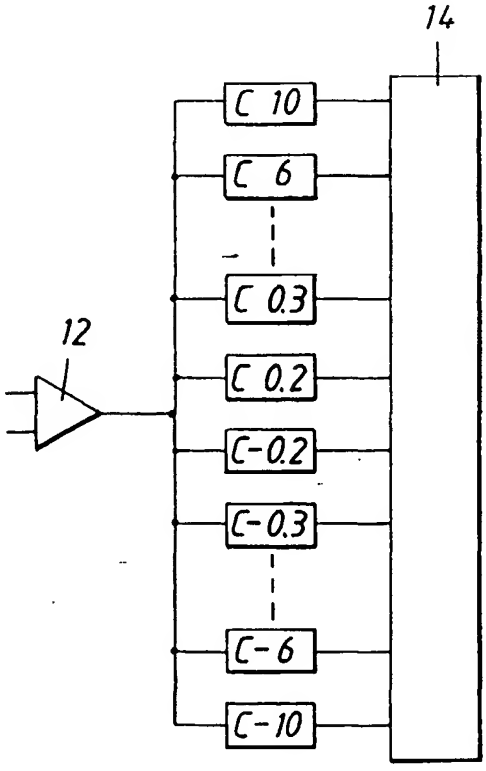

Fig. 4

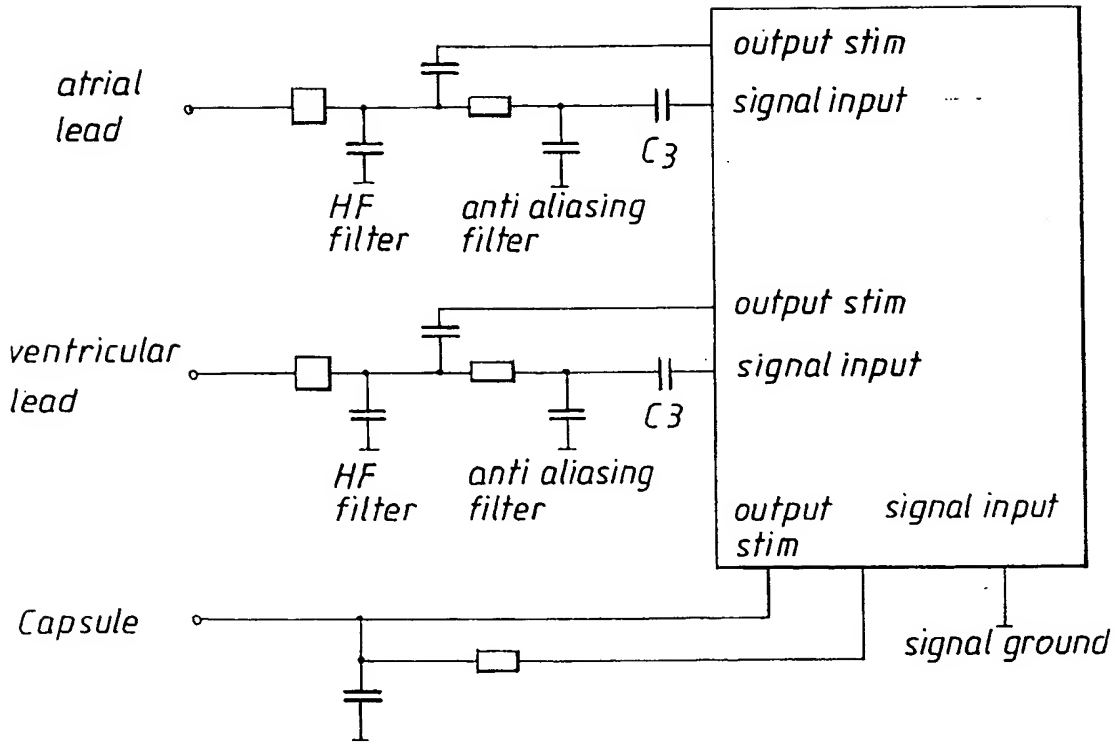

Fig. 5

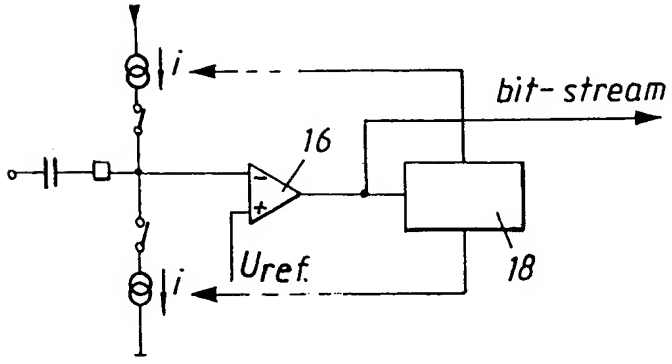

Fig. 6

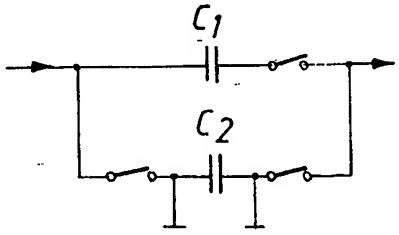

Fig. 7

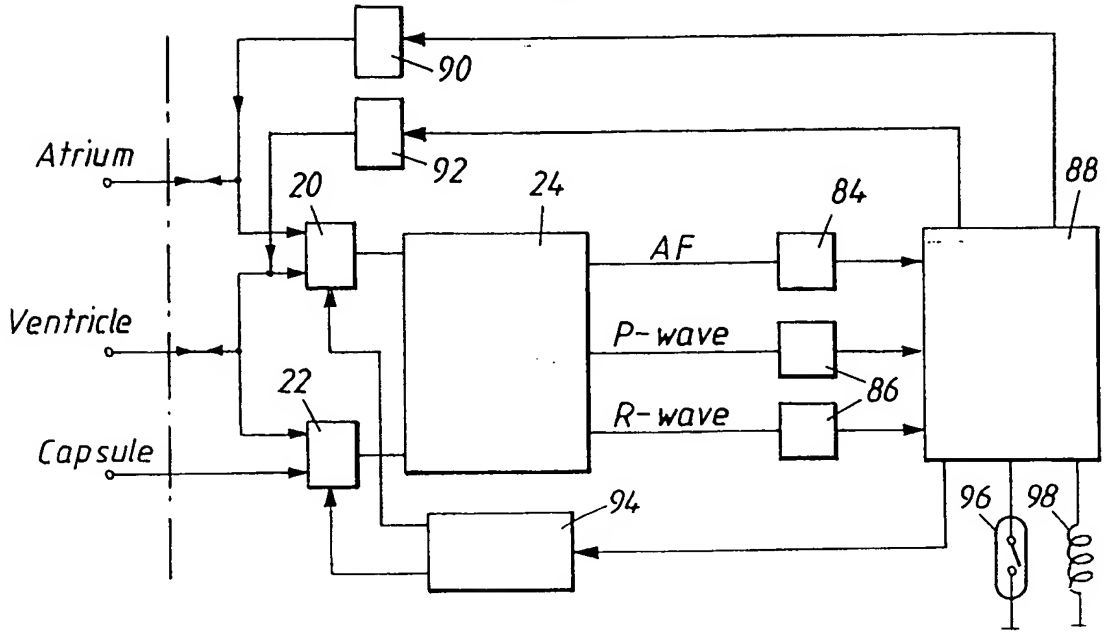
90
92
Atrium
20
24
84
88
AF
Ventricle
P-wave
86
22
R-wave
Capsule
94
96
98

Fig. 8

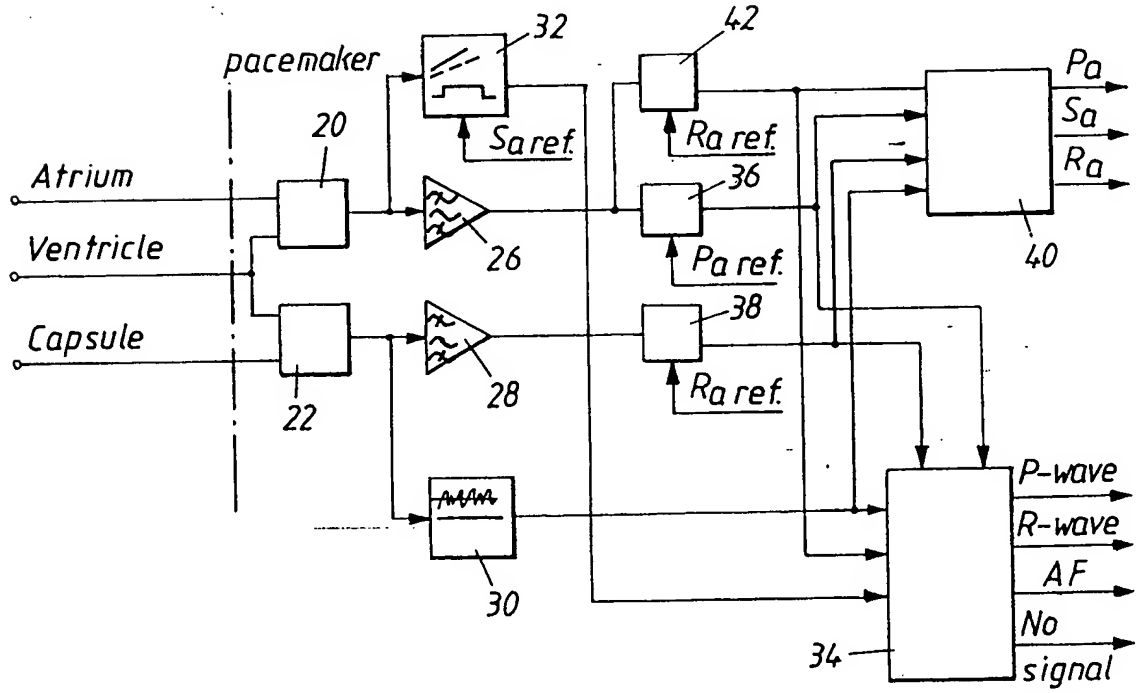
pacemaker
32
42
Pa
Sa
Ra
20
Sa ref.
Ra ref.
Atrium
36
Ventricle
26
Pa ref.
40
38
Capsule
Ra ref.
22
28
P-wave
R-wave
AF
No
signal
30
34

Fig. 9

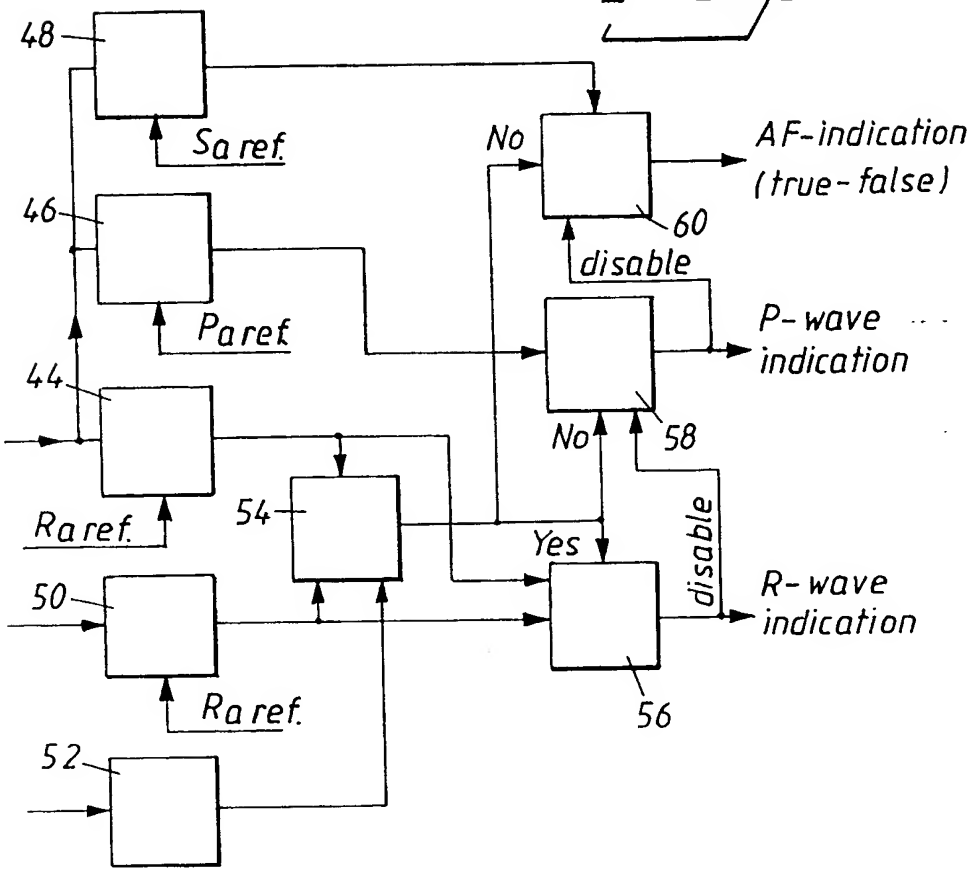
48
Sa ref.
46
Pa ref.
44
Ra ref.
54
50
Ra ref.
52
No
60
AF-indication
(true-false)
disable
P-wave
indication
No
58
Yes
disable
R-wave
indication
56

Fig. 10

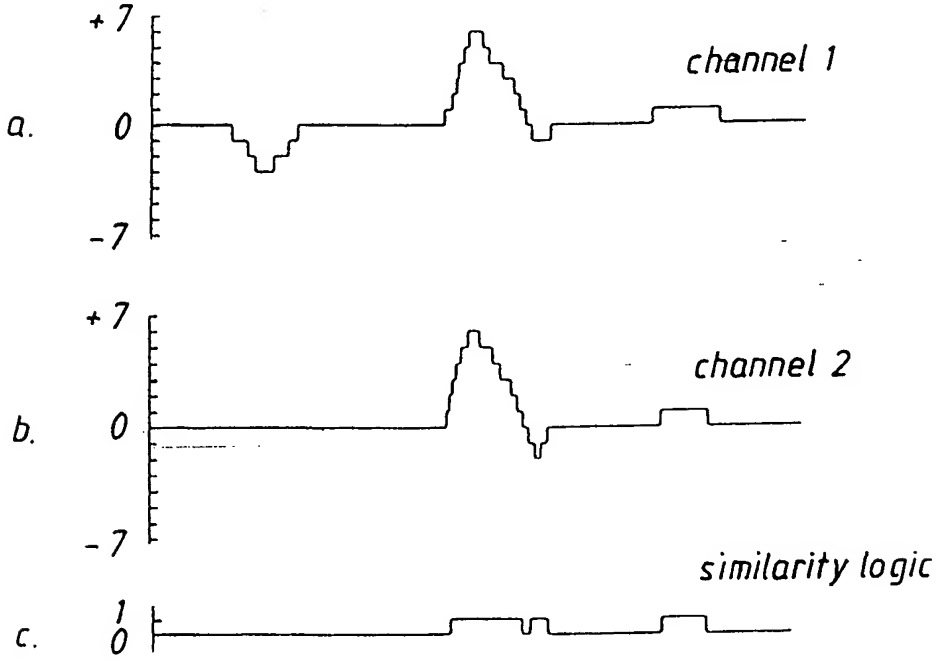
+7
a.
0
-7
channel 1
+7
b.
0
-7
channel 2
similarity logic
c.
1
0

Fig.11

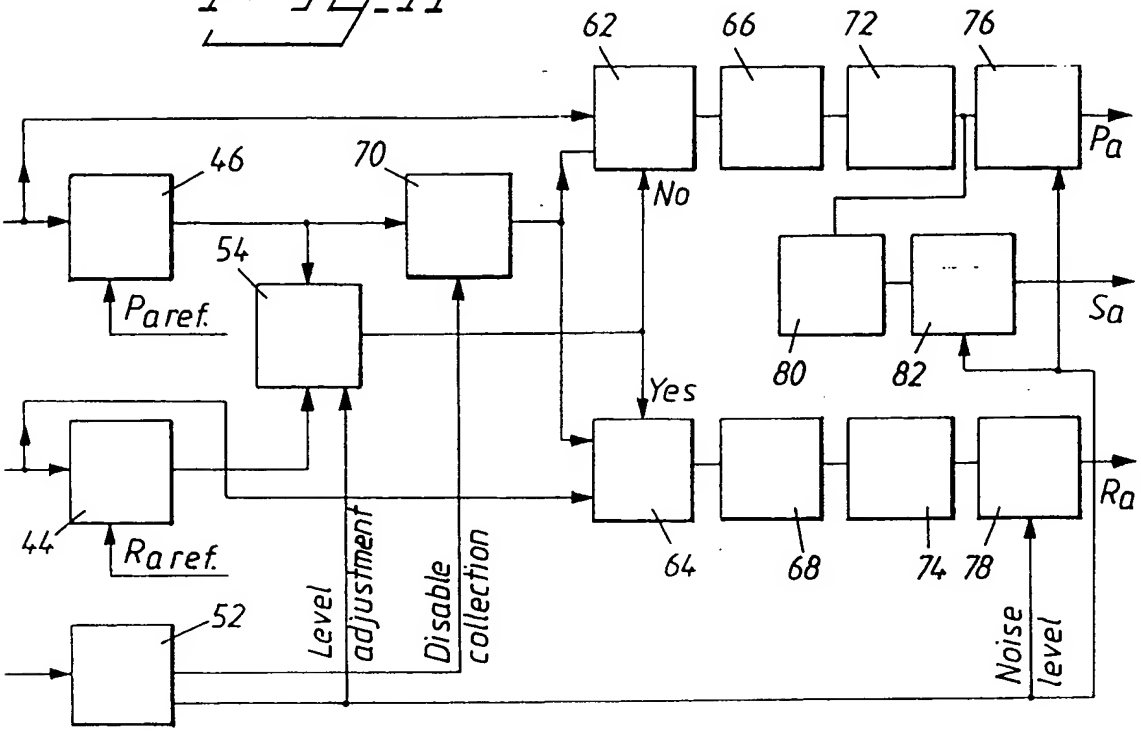

Fig.12

Table I

channel 1	channel 2	similarity
0	0	0
0	0	0
0	0	0
0	0	0
0	0	0
-1	0	0
-3	0	0
-1	0	0
0	0	0
0	0	0
0	0	0
1	2	1
6	5	1
7	7	1
2	3	1
-1	-1	1
0	0	0
0	0	0
0	0	0
0	0	0
0	0	0
1	0	0
1	1	1
1	1	1
1	0	0

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 98 12 0474.6

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
D,Y	EP 0646390 A1 (PACESETTER AB), 5 April 1995 (05.04.95) * column 3, line 3 - line 30; column 6, line 6 - line 27, abstract * --	1-27	A61N 1/368 A61B 5/0402
Y	WO 9739681 A1 (THE REGENTS OF THE UNIVERSITY OF MICHIGAN), 30 October 1997 (30.10.97) * page 5, line 25 - page 6, line 23, abstract * --	1-27	
D,A	US 5058599 A (H. ANDERSEN), 22 October 1991 (22.10.91) * see the whole document * --	1-27	
D,A	US 5607457 A (H. SCHüLLER), 4 March 1997 (04.03.97) * see the whole document * --	1-27	TECHNICAL FIELDS SEARCHED (Int. Cl.6) A61B A61N
D,A	EP 0596319 A1 (SIEMENS ELEMA AB), 11 May 1994 (11.05.94) * see the whole document * -----	1-9	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	12 January 1999	JONI SAYELER

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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